

Rapid setup and management of medical device design and manufacturing consortia: experiences from the COVID-19 crisis in the UK

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The COVID-19 pandemic caused severe ventilator shortages in many healthcare systems worldwide. The UK government reacted to this with a three-pronged approach of importing, up-scaling existing production and supporting new design projects. The latter two parts – labelled the UK Ventilator Challenge – included over 50 companies from various sectors including the automotive and aerospace industries. Nine multi-partner consortia and five single-company projects were initiated with varying approaches. This study explores lessons learned during the setup and management of these medical device designs and manufacturing consortia. A qualitative survey methodology was employed, and 32 semi-structured stakeholder interviews were conducted. The primary data was triangulated through the collection of 42 secondary data sources such as webinars and radio interviews. Transcription and a three-step data analysis process of thematic coding identified six lessons learned. The analysis of the data showed that a strong, appealing common goal can enable employee motivation and trust as well as align priorities across all companies involved. This facilitates the involvement and fruitful collaboration of companies with varying sizes and fields of expertise. Furthermore, selecting the most suitable employees with specialist knowledge for high-priority projects and empowering them to make decisions can have a positive effect on project performance. The findings from the study complement existing literature on new product development and crisis management processes. In addition, the results uncover potential long-term effects such as more openness for cross-sector collaborations, which can serve as interesting sources for further research.

1. Introduction

The outbreak and worldwide spread of the coronavirus SARS-CoV-2 and the resulting disease COVID-19 has caused global health-related shocks (WHO, 2020a). A study by Yang et al. (2020) suggests that approximately 76% of COVID-19-patients are asymptomatic or have only mild symptoms, while the remaining 24% develop severe and critical symptoms. These patients require different respiratory treatments, ranging from non-invasive options such as Continuous Positive Airway Pressure (CPAP) to sedation and intubation for mechanical ventilation (Yang et al., 2020).

In early March 2020, due to rapidly rising numbers of COVID-19 cases, the UK National Health Service (NHS) projected an urgent need for up to 30,000 ventilators, with just over 8,000 then actually available (Balogun, 2020; National Audit Office, 2020). In response, the UK government implemented a three-pronged strategy: (i) importing ready-made devices from overseas, (ii) scaling-up existing domestic production, and (iii) supporting the rapid development and manufacturing of new device designs. Since global ventilator supplies were very limited due to the pandemic, increasing imports proved ineffective and the latter two prongs – jointly labelled the ‘UK Ventilator Challenge’ (UKVC¹) – were given priority. Essentially, the government’s approach was to maximise speed and chance of success before considering costs (National Audit Office, 2020). This initiative brought together over 50 companies across diverse sectors ranging from medical devices (MD) to the automotive, aerospace and defense industries. From this community, five single company projects and nine multi-partner consortia projects were initiated as shown in Figure 1.

The EU regulations define MDs as: “any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings” (EU Parliament, 2017, p. 117/15). Ventilators fall into the second-highest regulatory classification (Class IIb) and are subject to multiple regulatory assessments such as CE-marking, clinical trials and an assessment of the technical documentation (EU Parliament, 2017). Notified Bodies are independent certification bodies designated by the National Competent Authority i.e. the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. While the MHRA is responsible for setting and enforcing the MD standards, testing and certification are handled by one of the three Notified Bodies in the UK. MD manufacturers also require certification of the ISO13485 quality management system (QMS). These requirements make medical device development (MDD) a complex and lengthy process associated with many uncertainties and high costs (Marešová et al., 2020).

The projects pursued different strategies regarding design and clinical sophistication. Some used existing or adapted designs, whilst others developed new devices ranging from emergency ventilators using resuscitation bags to more sophisticated ventilator designs exceeding the Rapidly Manufactured Ventilator System (RMVS) specification,² as shown in Figure 2. Striped projects successfully ran through the approval stages and collectively produced over 15,000 ventilators (National Audit Office, 2020). Out of the 11 new and adapted designs, four devices “achieved a performance level which met the [UK regulatory body] requirements” (Cabinet Office, 2020a). The remaining projects either did not meet the required



Figure 1. Overview of UKVC projects and involved companies (Brand logos from company websites).

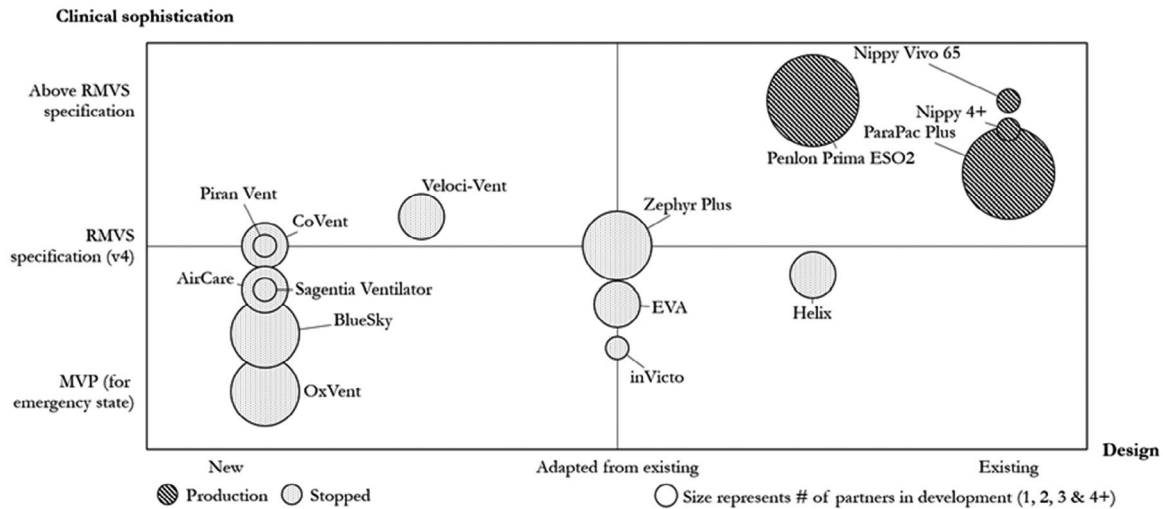


Figure 2. Design approaches & clinical sophistication levels of UKVC projects (excl. Gemini due to lack of information).

specification or were stopped due to lower than initially anticipated demand (Cabinet Office, 2020b). Early modelling (1st March 2020) of the reasonable worst-case scenario by NHS England and Improvement suggested the potential need for up to 90,000 mechanical ventilator beds at the forecasted peak of 13th April 2020. With the positive impact of mitigations such as social distancing, the anticipated urgent demand did not materialise and the forecast was lowered to 17,500 on 24th March 2020 (National Audit Office, 2020).

Successfully running through the design, development, regulatory and clinical trial stages in the MDD normally takes several years. While much research is concerned with MDD acceleration techniques under ‘normal’ conditions, collaboratively developing and manufacturing a complex, safety-critical Class IIb MD in response to a global public health emergency within extremely short time frames is less well addressed in the literature. To address this gap, a general research question (RQ) was formulated:

What can be learned from analysing the experiences of the rapid setup and management of medical device design and manufacturing consortia in response to the COVID-19 crisis?

The remainder of this paper is structured as follows. We review the literature to position this topic within existing research areas, outline the subsequent research gap and formulate a more precise research question. We then explain the choice of methodology and present the research design including data collection and analysis methods. Next, the findings of the primary and secondary data are presented and discussed by linking them back to the literature.

Finally, we draw the key conclusions, reflect on the limitations of this study and present possible areas for future research.

2. Literature review

This topic is positioned within three areas of knowledge: New Product Development (NPD) for MDs (MDD), crisis-response consortia within the broader literature on multi-partner collaborations, and the setup and management of NPD projects in the context of crises.

2.1. New product development and medical device development

Most of the UKVC companies demonstrated experience and advanced capabilities in NPD, but the regulatory and clinical requirements of MDs make development processes particularly challenging for organisations with little or no prior experience in the sector. Therefore, we explored prior work on the special characteristics and requirements of MDs and associated development processes.

Building on the developments in the literature around NPD, including the stage-gate system by Cooper (1990), various researchers have reviewed MDD processes and formulated multi-phase models (Pietzsch et al., 2009; Medina et al., 2013; Ocampo and Kaminski, 2019). Since regulatory requirements and pathways vary significantly for different MDs and regulatory bodies, there is no consistent understanding of the number of phases and their content. However, Marešová et al. (2020)

discovered that most studies identify five overarching steps: (1) Need assessment & Initiation; (2) Conceptualisation; (3) Design, Development & Production Planning; (4) Verification & Validation and (5) Production & Post-Launch. Hence, MDD involves a complex, multi-phase process (Marešová et al., 2020).

Since the MD industry is one of the most R&D intensive sectors with investments of around 7% of annual revenue (EvaluateMedTech, 2018), MD companies constantly search for critical success factors (CSFs) that facilitate a shorter time-to-market without losing quality and compliance. Table 1 summarises CSFs uncovered by several researchers that studied MDD processes in SMEs and large companies.

2.2. Multi-partner collaboration

Research identifies multi-partner arrangements as a key element of strategies to successfully manage certain types of public policy challenges (Bryson et al., 2015). In their recent study, Crick and Crick (2020) conclude that such collaboration models among rivals

can lead to performance-enhancing business models in response to crises such as COVID-19. The complex regulatory requirements of MDD require both successful cross-functional teamwork within companies (Holland et al., 2000) and the close involvement of different partners such as regulatory bodies.

Figure 3 summarises the different organisations/groups and their connections within the UKVC. The light grey box represents the UKVC project teams that were concerned with the MDD task, whereas the dark grey box includes the supply chain and assembly capabilities that were also required to build the ventilators. Outside the UKVC manufacturing ecosystem, the projects had to manage communication with government and regulatory bodies. To enable effective communication and inter-project coordination, the UK government appointed an intermediary organisation (PA Consulting). Due to the various stakeholders involved and since “cross-sector collaboration is hardly an easy answer to complex public problems” (Bryson et al., 2015, p. 648), the influencing dimensions and success factors of multi-partner

Table 1. CSFs identified in the MDD literature

Area of application	Authors	Study type	Critical success factors
Stage-gate process for MDD	Pietzsch et al. (2009)	>80 expert interviews	<ul style="list-style-type: none"> • Knowledge about regulatory requirements • Experience and skills of the engineers involved
Product design process model for MDD	Medina et al. (2013)	Expert interviews for model validation	<ul style="list-style-type: none"> • Effective execution of MDD process • User involvement in design reviews and verification
Evaluation of MDD success factors	Kirkire and Rane (2017)	DEMATEL methodology with expert interviews	<ul style="list-style-type: none"> • Availability of experts and their experience • Active involvement of stakeholders in all MDD stages • Complete elicitation of end-user requirements • Make clinicians “the partners in progress” • Level of integration of different functional departments of the organisation • Sound performance measurement system
Supply chain management (SCM) in medical technology sector	García-Villarreal et al. (2019)	Case study with 15 interviews	<ul style="list-style-type: none"> • Training and commitment of staff • Cooperation and knowledge exchange between OEM and supply chain • Appropriate information systems to support decision making in SCM • Efficient tracking and tracing of medical technology in the SC for quality and compliance • Reduction of complexity in the design of products and manufacturing processes

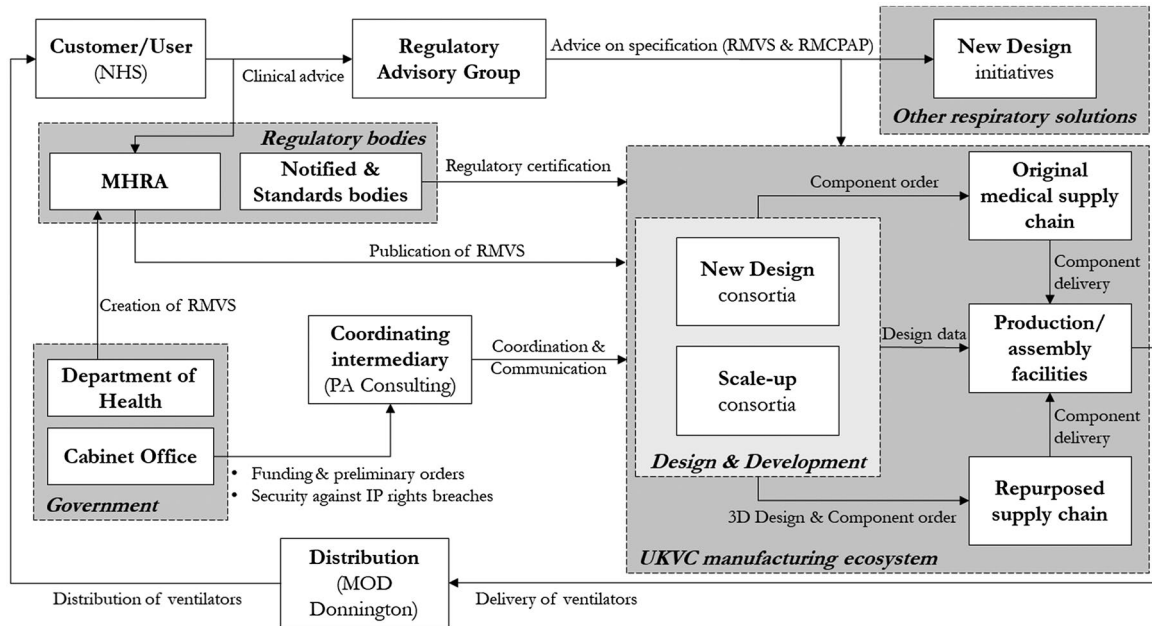


Figure 3. Stakeholder map of UKVC with different collaboration paths.

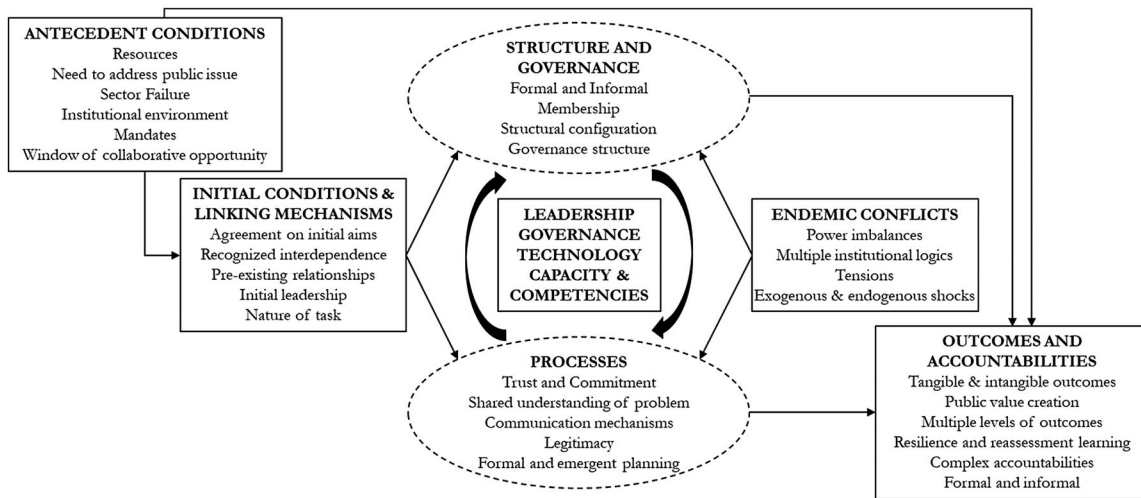


Figure 4. Synthesis of theoretical frameworks on cross-sector collaborations (Adapted from Bryson et al., 2015).

collaborations in the literature are reviewed in the following section.

To address the complexity of collaborations of organisations from different sectors, Bryson et al. (2006) formulated a theoretical framework describing conditions, structure and constraints. Following that, many scholars developed concepts emphasising different aspects of cross-sector collaborations. For example, Provan and Kenis (2007) focused on how modes of collaboration governance can address legitimacy to avoid evolving tensions between participants. Other studies focused on

communication practices (Koschmann et al., 2012) and leadership structures and processes (Agranoff, 2012). In 2015, Bryson et al. analysed the development of the research area and synthesised multiple theoretical and empirical studies in a joint framework (Figure 4).

Bryson et al. address the antecedent conditions that lead to the formation of collaborations such as the UKVC, where the MD sector was unable to meet the unexpected, enormous ventilator demand. Even with favourable antecedent conditions, the formation of collaborations still depends on specific

initial conditions such as pre-existing relationships which have a significant impact on collaboration structures. Furthermore, endemic conflicts such as multiple institutional logics need to be managed effectively for productive collaborations (Bryson et al., 2006).

In addition to the public value of synergising multiple sectors' capabilities, the outcome of cross-sector collaborations categorise into first-, second- and third-order effects. First-order effects are direct collaboration results such as new intellectual capital, while second-order effects occur outside project boundaries, e.g. joint learning. Lastly, third-order effects only become apparent in the long-term such as decreased destructive conflict (Innes and Booher, 1999).

2.3. Crisis management in NPD projects

With its rapid global spread, the World Health Organisation (WHO) declared COVID-19 as a "public health emergency of international concern" (PHEIC) on 30th January 2020 (WHO, 2020b). According to the WHO, an emergency is "a state in which normal procedures are suspended and extraordinary measures are taken to avert a disaster" (WHO, 2002, p. 10). In comparison, a disaster is defined as "an occurrence disrupting the normal conditions of existence and causing a level of suffering that exceeds the capacity of adjustment of the affected community" (WHO, 2002, p. 3). The terms emergency, disaster and crisis are "closely interconnected, interdependent and overlap significantly" (Al-Dahash et al., 2016, p. 1191), in that an emergency can turn into a disaster, while a disaster is inherently an emergency.

The shortage of ventilators during the COVID-19 pandemic can be portrayed as a crisis situation. Pedersen et al. (2020, p. 315) define "a crisis as a sequence of events that can have substantial negative consequences if not managed appropriately". For NPD, crises are caused by undesired and unexpected events and are connected with high time and result pressure (Lindemann, 2009). They can exist on technical, social, or organisational levels and affect the ability to reach important milestones in the development process. Such crises can be caused by worker shortage, uncertainty of information or stress and anxiety related to the threatening nature of the crisis (Muenzberg et al., 2016). While many crises have an economic aspect, the COVID-19 crisis impacted organisations differently, as investigated by Cortez and Johnston (2020) who identified the main differences between prior financial-based crises such as the 2008–2009 subprime crisis and

the COVID-19 crisis: The COVID-19 crisis is characterised by (i) a focus on the individual humans rather than the business and (ii) a highly disrupted everyday life for whole populations with significant government interventions such as quarantines and temporarily closed businesses (Cortez and Johnston, 2020). Combined with the need for remote working and virtual communication, the unknown time span of COVID-19 pandemic impacted business operations severely.

Despite major events such as 9/11 or the 2008–2009 subprime crisis, there is a surprising lack of research focusing on crisis management (Pedersen et al., 2020). Regarding crisis management in NPD projects, Akgün et al. (2006) investigated 319 NPD teams and concluded that a perceived crisis is positively linked to new knowledge creation. In a later study, Akgün et al. (2007) found that a high degree of management support facilitates speed-to-market and new product success. A recent study by Samra et al. (2019) suggests that a high level of perceived crisis can result in better new product performance. Muenzberg et al. (2016) provided the first detailed study of NPD crises by analysing 15 industrial NPD projects, in which participants reported crises of diverse natures. Within these, the environment and causes of the crisis, the crisis itself and the effects of the crisis were investigated. Eight common context factors were identified as shown in Table 2.

2.4. Key issues arising from the literature review

The literature on MDD predominantly deals with effectively managing the information inputs from multi-disciplinary stakeholders. To shorten time-to-market, various studies have researched CSFs in the MDD process. The literature on multi-partner collaborations is well developed with varying forms and characteristics. Factors such as institutional logics and trust among collaborators are considered crucial for collaboration success. Lastly, NPD crisis management is a nascent literature area that deals with the adaptation of project management to successfully solve crises. Factors such as the level of perceived crisis and the degree of management support have been identified to influence NPD performance.

2.5. Research gap

Drawing upon the concepts identified in the literature review and contextual data relating to COVID-19 in

Table 2. Context factors and CSFs for NPD crises (Muenzberg et al., 2016)

Context factors	Critical success factors
Project risk <ul style="list-style-type: none"> Caused by high result & time pressure and unclear information situation 	Corporate level <ul style="list-style-type: none"> Good corporate culture Securing sufficient capacities Support with decisions making by top management
Priority & Management support <ul style="list-style-type: none"> Caused by far-reaching consequences and high result & time pressure 	Project level <ul style="list-style-type: none"> Clear, short, quick, and timely communication Managers should give clear targets Experienced and authentic team leader Experienced team members Team leader should show trust to his team members
Degree of motivation/ morale, Project motive, Motivation <ul style="list-style-type: none"> Caused by far-reaching consequences, high project priority for damage prevention, and management attention 	<ul style="list-style-type: none"> Flexibility “Careful” openness Ability to work under pressure Trust on all levels
Reward and recognition <ul style="list-style-type: none"> Caused by high project risk, high project priority, high internal & external recognition and high reward for crisis solvers ‘fire fighters’ 	Personnel level <ul style="list-style-type: none"> Network: colleagues, external partners Reliable network Communication with the right persons Start early communication Communication with the customer Early integration of all relevant partners
High pressure to succeed <ul style="list-style-type: none"> Caused by far-reaching consequences and ‘must not’ fail project 	
Individual time pressure <ul style="list-style-type: none"> Caused by high result, time pressure, and higher workload & longer working hours 	
Coordination and division of work <ul style="list-style-type: none"> Caused by high project priority, high risk, decoupling from ‘daily business’ and need of special competences 	
Type of project control <ul style="list-style-type: none"> Caused by management attention & support, high motivation, and direct report to and control by management control 	

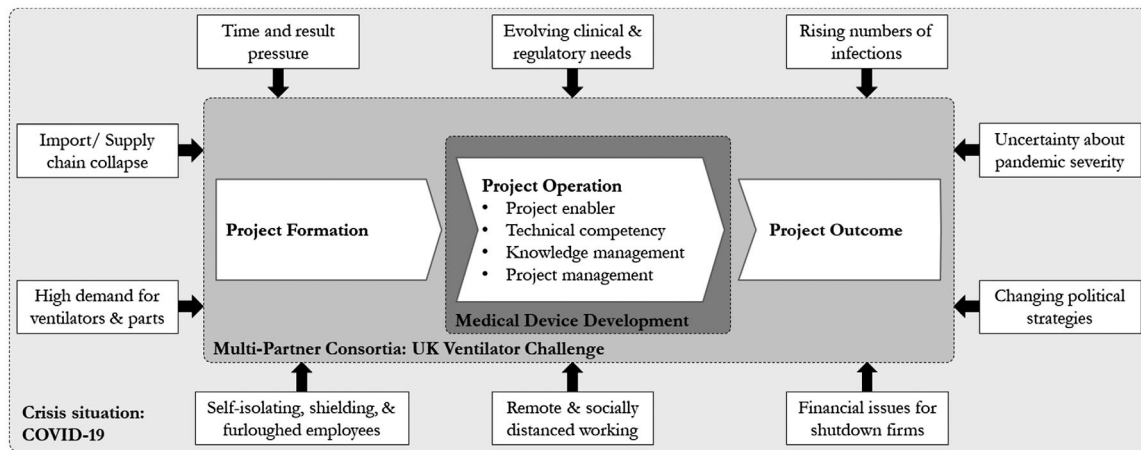


Figure 5. Conceptual framework for analysing the UKVC.

the UK, Figure 5 summarises the issues and their interconnectivity relating to the UKVC projects. The COVID-19 pandemic affected the two inner levels with various challenges such as uncertainty and result pressure. In the middle layer, the setup and management of consortia is divided into the phases of project formation, operation and outcome. During the project operation phase, the projects faced the MDD process, which is separated into technical competency, project enablers as well as project and knowledge management. In this process, the efforts

and capabilities of the involved organisational groups needed to be effectively aligned. The project outcome phase encompasses the short-term to long-term outcomes (e.g. addressing short-term ventilator shortage through to regulatory framework changes to support future crisis responses).

Prior research on developing and building Class IIb MDs in extremely short timeframes using non-specialist capabilities and under the constraints of a global pandemic is very limited. Some parallels with UKVC can be observed from analysis of the polio

pandemic that infected, paralysed and killed thousands of children around the world. When the epidemic hit Australia in the 1930s, the so-called 'Iron Lung' – a negative pressure ventilator developed by Drinker et al. in the late 1920s – was deemed too heavy, bulky, and expensive. As a result, Edward and Donald Both rapidly developed a simplified Iron Lung made of plywood at a fraction of the cost (Markel, 1994). In following polio outbreaks around the world, further advancements in mechanical ventilation were achieved by individual engineers (Slutsky, 2015; Wertheim, 2020). As such, a research gap could be identified in that, so far, little research has been conducted to investigate lessons learned in disaster response manufacturing consortia. The detailed research question is therefore:

What lessons can be synthesised from the rapid setup and management of the medical device design and manufacturing consortia to support future rapid design and scale-up projects?

3. Research method

3.1. Research strategy & design

To explore the experiences of the different UKVC stakeholders, various research methods outlined by Yin (2009) were considered. Since this study focuses on contemporary events and the researcher has no control over the events, the survey method was chosen to obtain a comprehensive picture of the experiences and facilitate differential comparisons in settings and approaches.

3.2. Data collection

At the outset, stakeholders on project management and team member levels such as designers and engineers were targeted with the aim of higher responsiveness and availability as compared to top management stakeholders. However, due to a high level of media interest, many stakeholders had signed non-disclosure agreements, which meant that some individuals on operational levels within UKVC organisations were hesitant to contribute to this research. In contrast, most top management stakeholders showed a high level of interest in the research project, were willing to share their experiences, and were able to comment on operational project aspects.

To triangulate the perspectives of the multi-partner consortia, stakeholders in the wider collaboration network (as shown in Figure 3), including regulatory and policy experts, suppliers delivering

to multiple consortia and stakeholders from non-government supported projects with other respiratory solutions such as negative-pressure ventilators were interviewed. In total, 32 interviews with stakeholders from 30 different organisations were conducted. Table 3 illustrates the sources of both primary and secondary data. Personal information was anonymised, and interviewee codes used that linked the individual to a specific project and role.

In addition to the primary data collection, an extensive secondary data collection was conducted. Due to the large public interest in the different projects, many stakeholders were questioned to reflect on experiences in radio interviews, podcasts or webinars. Lastly, many companies published case studies elaborating on lessons learned. In this way, over 50 secondary data sources from companies involved were recorded and filtered for relevance to the RQ, resulting in 42 selected sources of secondary data. Both primary and secondary data collection was completed in the time span from May to August 2020.

3.3. Data analysis

Primary and secondary qualitative data was analysed following the "Gioia method" using the coding software Nvivo (Gioia et al., 2013). In this three-step process, the first step involved identifying themes in the raw data and summarising them in coding nodes. The first iteration of coding reduced the data to quotes, sentences or paragraphs that proved relevant to the RQ. The data was clustered into different coding types. Data that provided information about the projects was labelled as contextual. Furthermore, lessons learned from overcoming encountered challenges were identified and differentiated between specific to the UKVC-situation and applicable to future design and development projects. Subsequently, the created nodes were analysed for overarching topics and regrouped accordingly. Then, the second iteration of coding was performed to identify previously overlooked passages. Lastly, the codes were organised following overarching categories, each containing multiple codes with lessons learned. These were then analysed by comparing interviewee quotes and triangulating them with the secondary data. The results were then interpreted in the context of existing literature.

4. Findings and discussion

In this section, we present and discuss the results of the data analysis focusing on the project operation

Table 3. Overview of the data collection

	Perspective	Function	Scale-up	New & adapted design
Primary data (Total=32)	Inside project	Design/IT	1	2
		Human Factors	1	2
		Manufacturing & Assembly	4	1
		Supply Chain Management	1	1
		Top Management	6	4
	Total inside project interviews		13	10
	Outside project	Supplier	1	3
		Experts (Regulatory & Policy)	2	
		Other respiratory solutions	3	
	Total outside project interviews		9	
	Type		Scale-up	New & adapted design
Secondary data (Total = 42)	Secondary interview		7	1
	Video		5	3
	Podcast/Online Q&A		7	1
	Case Study/Webinar		9	9

phase of the conceptual framework (Figure 5). Lessons learned from the four identified categories are illustrated with interview quotes (in italics) and discussed by linking them to the existing literature.

4.1. Project enablers

The challenges of convening organisations from diverse sectors with different ways of operating to work collaboratively emerged clearly from the data, and this is a well-reported topic in the literature (e.g. Holland et al., 2000). However, interviewees described how the national imperative overrode many of the more normal commercial, selfish behaviours, resulting in altruistic behaviours which interviewees described as “*no Not-Invented-Here*”, “*no-blame culture*” and “*egoless behaviours*”. The importance of such factors for effective collective group-thinking has been demonstrated in prior research (e.g. Holland et al., 2000), but it is acknowledged that the application in business “may seem like an unattainable goal to those with extensive experience of the pathologies of group life” (Hamilton and Zammit, 2008, p. 44).

Another important factor is trust, described by Bryson et al. (2015, p. 653) as the “essence of collaboration”. Since the different UKVC projects involved collaborations of partners with and without pre-existing relationships, projects started with varying degrees of trust. Many respondents identified the nationwide, common goal to deliver ventilators as one of the key collaboration drivers. The importance of this “*single, easily understood, [...] very compelling*

objective” was noted widely in the data. Interviewees stated how this helped enable a culture that reduced commercial competitive tensions and encouraged accessing and applying the best resources available. This phenomenon is often referred to as “collective goals” (Bryson et al., 2015, p. 649). Nevertheless, it was also noted by interviewees that such a trust-based culture was not established immediately and building that trust was something that required support. The team at VCUK described the process of “*norming, storming, performing*” referring to the model established by the psychologist Bruce Tuckman (1965) describing the transformation process of groups to high-performance teams.

The UKVC illustrates issues common to the setup of any collaborative NPD project. However, this case also highlights the amplifying effect of having a compelling, easily understandable, easily communicable message on the development of trust between partners and willingness to actively suppress potentially negative behaviours.

4.2. Technical competency

MDD processes generally start with the elicitation of clinical requirements and end-user needs (Pietzsch et al., 2009; Kirkire and Rane, 2017). Due to the novel nature of COVID-19, clinical understanding evolved during the UKVC. The UK Department of Health created an initial RMVS which was described by one interviewee as “*a mishmash of all of the ISO standards for ventilators*”. The MHRA had what

was described as an “*unenviable position, balancing risk-benefit and an emergency situation with much less time than normal to review applications*”. As the understanding of the clinical requirements of COVID-19 patients evolved, the RMVS specification was updated three times within three weeks as shown in Figure 6.

To react to the changing requirements, the application of specialist knowledge – not only MD-specific – was necessary. For the UKVC, some organisations from non-MD sectors found that their own operating environment had parallels with those of MDs and hence some barriers were lower than for other organisations. For example, aerospace companies were already used to operating a highly regulated, safety-focused environment. Motorsport companies have some of the quickest turnaround times between design and prototype which made them well suited for the rapid prototyping of ventilator components (Anderson, 2020). As argued by Preikschas et al. (2014), fighting against a crisis by combining the resources of different firms in industrial relationships can enable goals to be achieved that could not be achieved alone. Hence, these companies were able to leverage their expertise in a new project environment.

Nevertheless, the involvement of the original equipment manufacturer (OEM) ventilator companies (e.g. Smiths Medical and Penlon) in the scaling-up process was critical to help the consortia navigate the complex regulatory paths at the heart of MD design and manufacture. However, these specialist ventilator firms had limited bandwidth to support others as they were focused on scaling up their own production. Hence, involving additional MD manufacturers such as Siemens Healthineers and Inspiration Healthcare helped to support non-MD consortia members, for example, with ensuring compliance with MD certification. Kirkire and Rane (2017) highlighted the importance of such readily accessible regulatory expertise for MD development. Ventilators also have to be manufactured according to specific MD QMS (e.g. ISO13485). Hence,

non-MD manufacturers needed to be audited and certified before they could produce any MDs. In the VCUK, this process was accelerated by creating a list with all of the different QMS for defence as well as the aerospace and automotive sectors, which facilitated the identification of gaps between the QMS for the MHRA and the Notified Bodies.

By engaging in the UKVC, many of the involved SMEs reported that working with the larger manufacturing firms had allowed them to demonstrate their capabilities, and this had resulted in the development of new collaborative opportunities. In addition, the experience of working with organisations from different sectors led some organisations to report a desire to explore further cross-sector opportunities, something that they felt they were unlikely to have done prior to involvement in the UKVC.

The UKVC therefore illustrates three key issues relating to technical competency in collaborations. Firstly, having easily accessible and appropriately sophisticated domain-specific MDD expertise within the consortium was essential to ensuring focus on the key issues. Secondly, while it would have been ideal if all partners had expertise in MDD, this was not possible as the UK MD sector is not sufficiently large. However, drawing in partners from sectors with cognate characteristics (e.g. aerospace and motorsport, where adherence to safety standards and regulations is also fundamental) ensured that cultural and operational barriers between MD and non-MD partners were minimised. Finally, the UKVC allowed smaller firms to demonstrate their potential as partners for future collaborative projects with firms with which they might otherwise have struggled to engage.

4.3. Knowledge management

UK-wide lock-down restrictions meant that remote working had to be adopted widely for the UKVC. Despite face-to-face dialogue being “[...] at the heart of a process of building trust, mutual respect, shared understanding, and commitment to the process”

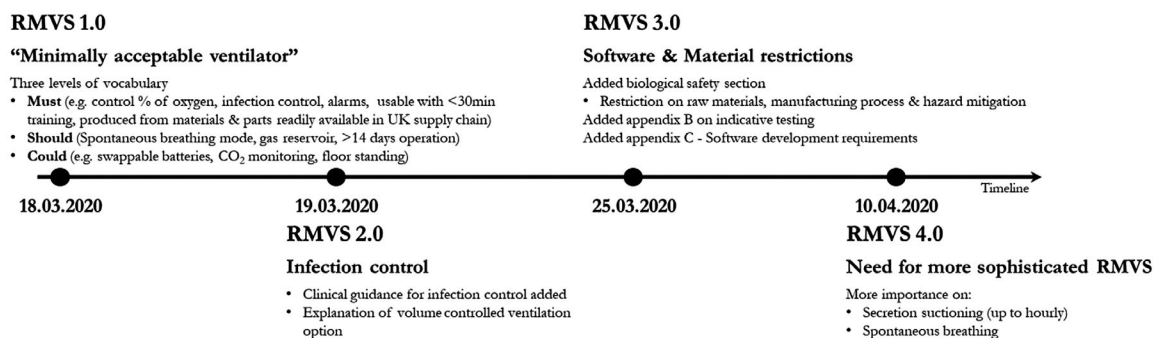


Figure 6. RMVS specification versions (Source: MHRA website).

(Ansell and Gash, 2007, p. 558), the consortia had to ensure that all those who could do so were able to work from home. Digital communication software (e.g. Microsoft Teams) was rapidly rolled-out and structured to enable the separation between private and public channels so that IP-sensitive information could be readily shared with selected team members.

An important aspect for most projects was the ability to capture and transfer MD-specific tacit and explicit knowledge to people from non-MD industries. This included knowledge about compliance-relevant material handling and documentation as well as the training of manufacturing and assembly staff. The shift from low volume to very high volume production at a high skill level caused the need to capture, as one interviewee put it, “*tacit knowledge [...] that has never been captured because it didn’t need to be*”. The need to transfer tacit knowledge is well-explored in collaborative NPD (Ramesh and Tiwana, 1999; Emden et al., 2006) but to facilitate the transfer and conversion of knowledge, Noran (2014, p. 1034) concludes that “the only current solution appears to be the regular immersion of the participant organisations in each other’s cultures”. In the VCUK, digital technologies such as virtual/augmented reality (VR/AR) enabled, for example, the Penlon team to remotely assist the Ford people working on the assembly line. Other digital tools included electronic documentation as well as digital modelling and simulation of production and assembly lines which enabled rapid digital validation for the implementation of measures such as social distancing.

Whereas some research argues that knowledge-related barriers such as the recipient’s lack of absorptive capacity play a major role in inhibiting knowledge sharing (Szulanski, 1996), Siemsen et al. (2008) underline the pivotal role of motivation in inter-employee knowledge sharing. Using a constraining-factor logic of the motivation-opportunity-ability (MOA) model, their empirical research shows that very high motivation can enable employees to overcome potentially constraining factors such as time pressure or virtual communication. In this case, the strong common goal stimulated employees’ motivation with neither constrained opportunity (e.g. time pressure) nor the lack of ability (thanks to using the “*strongest-athletes for the task*” as explained in chapter 4.4) limiting effective knowledge sharing.

Another major challenge noted during the analysis was the presence of supply chain bottlenecks around ventilator components since manufacturers around the world were all procuring similar parts. Established MD suppliers experienced a huge rise in demand, with some of it being real some of it being ‘phantom’: e.g. one MD component supplier

reported almost thirty different and uncoordinated avenues of inquiry which turned out to all relate to one single project. Moreover, some suppliers noted challenges arising from a lack of supplier involvement in some projects causing multiple re-works since suppliers were unable to understand the technical requirements of some components. Exchanging knowledge and closely cooperating with the supply chain can overcome these bottlenecks, as previously identified by García-Villarreal et al. (2019).

4.4. Project management

The new design projects faced a design and development task that usually takes multiple years but was compressed into a timeline of six weeks, while scale-up projects had to produce an estimated ten years’ worth of normal ventilator production within the space of three months.

Interviewees noted three factors which contributed to project acceleration: high and aligned priorities, strong leadership skills, and highly capable project members. In normal business, as described by one interviewee, it would be: “*[...] very rare [...] that this kind of group would be given the same priority, [...] not focusing on anything else*”, which is reflected in the literature on NPD crisis management (Muenzberg et al., 2016). The benefits of senior management involvement and strong leadership skills, including political and stakeholder management, have been identified in many research areas, especially cross-functional teamwork (Holland et al., 2000), MDD processes (Ocampo and Kaminski, 2019), and NPD crisis management literature (Akgün et al., 2007).

Lastly, the ability to access what was described by one interviewee as: “*the strongest athlete for the task*” was highlighted as essential for the success of the UKVC projects. The benefits of the right “skills of [the] engineers [...] involved” (Pietzsch et al., 2009, p. 021004-1) have been noted in the MDD literature which also outlines how difficult this is to emulate for more routine projects. With the tight timescales, decision-making needed to be fast-tracked which was achieved by empowering team members with an appropriate level of autonomy needed for rapid decision-making. Hence, decisions were not made top-down but placed at what one interviewee called “*[...] the point of greatest knowledge*”, reflecting what is observed in the literature (Ocampo and Kaminski, 2019).

5. Conclusions

In the history of mechanical ventilation, major public health emergencies such as the polio epidemic

led to major advancements in mechanical ventilation (Slutsky, 2015). This paper has sought to answer the question: *What lessons can be synthesised from the rapid setup and management of the medical device design and manufacturing consortia to support future rapid design and scale-up projects?* This question was addressed through the collection and analysis of primary data from 32 semi-structured interviews with stakeholders and 42 sources of secondary data. As summarised in Table 4, thematic coding of the transcripts yielded six major lessons learned.

5.1. Managerial implications

The findings in Table 4 complement known factors identified in prior research but illustrate lessons for managers of NPD and scale-up projects that can be drawn from their application in an extremely challenging ‘high pressure’ context. For example, this research showed the positive impact of having a common, easily communicable goal which can help override disagreements that may arise from differing company-specific interests of partners in any NPD collaboration. In addition, this research highlighted the way in which new staffing models for urgent and high-priority NPD projects could draw upon the selective use of the “*strongest athlete for the task*”. Analysis of the consortia also showed how the use of devolved leadership models, which allow decision-making “*at the point of greatest knowledge*” rather than more traditional hierarchies, can

avoid delays and support the acceleration of NPD project outcomes.

5.2. Limitations

This research is exploratory in nature, relied predominantly on qualitative data from interviews and selected secondary sources, and was focused on a unique context. As such, the generalisability of findings is limited. The research was also undertaken in the midst of the COVID-19 lockdown in the UK, and sought to capture data from a live and high-pressure project. As a result, interviews were limited in time and covered topics in varying depth and breadth. Furthermore, stakeholders might have felt obliged to adhere to official corporate views in some of their responses. Primary and secondary data was collected in the period of May to August 2020. Given the high profile of this project, and level and speed of public expenditure, on-going public reviews will no doubt reveal further insights that will require additional analysis. The cross-sectional nature of the study also limits the ability to infer causality of the observed phenomena.

5.3. Further research

The exploratory and qualitative nature of the study means that it is not possible to draw widely generalisable nor definitive conclusions from the analysis. To validate the findings of this study, a quantitative study with a larger sample size could provide

Table 4. Summary of key findings

CSFs identified in literature review	Findings from the study
Managers should give clear targets (Muenzberg et al., 2016)	Strong, appealing common goal reduced competitive tension, facilitated trust and ensured access to the best resources
Common organisational objective (Holland et al., 2000)	
High level of perceived crisis can result in better NPD performance (Samra et al., 2019)	
Different organisational cultures can act as drivers of crises in collaborative NPD (Lynch et al., 2014)	The involvement & collaboration of companies of different sizes and varying expertise can have mutually beneficial long-term effects
Face-to-face communication is essential for trust, mutual respect and commitment (Ansell and Gash, 2007)	Crucial role of employee motivation, supported through digital tools and highly capable employees, to ensure effective knowledge sharing
Knowledge sharing behaviour among employees can be restricted by their motivation, opportunity or ability (Siemsen et al., 2008)	
Cooperation and knowledge exchange between OEM and supply chain (García-Villarreal et al., 2019)	Early and open involvement of suppliers needed to avoid bottlenecks
Experts & their expertise needed (Pietzsch et al., 2009; Muenzberg et al., 2016; Kirkire and Rane, 2017)	Being able to choose the experienced specialists facilitates productivity – ‘ <i>pick the strongest athlete for the task</i> ’
Management attention and support needed (Akgün et al., 2007; Muenzberg et al., 2016)	Maximum productivity achieved through empowerment of team members – ‘ <i>put the decision at the point of greatest knowledge</i> ’
Strong leadership skills required for successful MDD (Ocampo and Kaminski, 2019)	

more generalisability. Given the pandemic nature of COVID-19 and the numerous consortia formed globally to address similar challenges to those faced in the UK, there are multiple opportunities for such research to be undertaken.

Delving more deeply into the tentative long-term outcomes could also serve as a source of further research. The experiences in the UKVC may lead to similar cross-sector collaborations tackling national and international policy in relation to 'grand challenges' such as climate change. Moreover, companies involved in the UKVC may be more open to leverage synergies from commercial cross-sector collaborations. A longitudinal study, following collaborative NPD or MDD projects in companies that were involved in the UKVC, could be another avenue of exploration.

Acknowledgements

The authors thank Dr Lucia Corsini, Dr Mukesh Kumar, Dr Carlos Lopez-Gomez and Dr Jennifer Castaneda Navarrete for their valuable contributions to the background research for this paper and for their inputs on the early drafts of this paper.

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Notes

¹Somewhat confusingly, one of the individual UKVC consortia decided to name itself the ‘Ventilator Challenge UK’ (VCUK).

²<https://www.gov.uk/government/publications/specification-for-ventilators-to-be-used-in-uk-hospitals-during-the-coronavirus-covid-19-outbreak/rapidly-manufactured-ventilator-system-rmvs>

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